

David E. De Lorenzi  
Sheila F. McShane  
**GIBBONS P.C.**  
One Gateway Center  
Newark, New Jersey 07102-5310  
(973) 596-4500

Of Counsel:

Matthew D. Powers, Esq.  
**WEIL, GOTSHAL & MANGES, LLP**  
201 Redwood Shores Parkway  
Redwood Shores, California 94065  
(650) 802-3000

Nicolas G. Barzoukas, Esq.  
Jason C. Abair, Esq.  
Audrey L. Maness, Esq.  
Joshua P. Davis, Esq.  
**WEIL GOTSHAL & MANGES LLP**  
700 Louisiana, 16<sup>th</sup> Floor  
Houston, Texas 77002  
(713) 546-5000

*Attorneys for Plaintiff*

**IN THE UNITED STATES DISTRICT COURT FOR THE  
DISTRICT OF NEW JERSEY**

_____	)	
SCHERING CORPORATION,	)	
	)	
Plaintiff,	)	
	)	Civil Action No. 09-6373 (GEB) (TJB)
v.	)	
	)	
APOTEX INC. and APOTEX CORP.,	)	
	)	
Defendants.	)	
_____	)	

**SCHERING CORPORATION'S REPLY TO COUNTERCLAIMS CONTAINED IN  
APOTEX INC. AND APOTEX CORP.'S ANSWER**

Plaintiff Schering Corporation (Schering) responds as follows to each of the numbered paragraphs of the Counterclaims contained in the Answer of Defendants Apotex Inc. and Apotex

#1477103 v1

105686-67911

Corp. (collectively, Apotex) to Schering's Complaint, as set forth in Apotex's ANSWER TO COMPLAINT, SEPARATE DEFENSES, COUNTERCLAIMS AND DEMAND FOR JURY TRIAL:

**PARTIES**

1. Apotex Inc. is a corporation existing solely under the laws of Canada, having its only places of business located in Canada, including at 150 Signet Drive, Weston, Ontario M9L 1T9, Canada.

**REPLY:** Based on information from Apotex, Schering admits that Defendant Apotex Inc. is a Canadian company with offices at 150 Signet Drive, Toronto, Canada M9L 1T9. Schering lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 1, and Schering therefore denies these allegations.

2. Apotex Corp. is a Delaware corporation, having a place of business at 2400 North Commerce Parkway, Suite 400, Weston, Florida 33326.

**REPLY:** Admitted.

3. On information and belief, Schering Corporation purports to be a corporation organized and existing under the laws of the State of New Jersey, with a principal place of business at 3070 US Highway 22, Branchburg, New Jersey 08876.

**REPLY:** Schering admits that it is a New Jersey corporation and that it has a place of business at 3070 U.S. Highway 22, Branchburg, New Jersey 08876.

**JURISDICTION AND VENUE**

4. These Counterclaims arise under the Patent Laws of the United States, 35 U.S.C. § 1 et seq., and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

**REPLY:** Admitted.

5. This Court has original jurisdiction over the subject matter of these Counterclaims under 28 U.S.C. §§ 1331 and 1338(a).

**REPLY:** Admitted.

6. This Court has personal jurisdiction over Schering because Schering has availed itself of the rights and privileges of this forum by suing Apotex in this District, and because Schering conducts substantial business in, and has regular and systematic contacts with, this District.

**REPLY:** Admitted.

7. Venue is proper in this District under 28 U.S.C. §§ 1391(b) and 1400(b).

**REPLY:** Admitted.

### **PATENTS-IN-SUIT**

8. On or about November 17, 1998, the United States Patent and Trademark Office (“PTO”) issued U.S. Patent No. 5,837,699 (“the ‘699 patent”), entitled “USE OF MOMETASONE FUROATE FOR TREATING UPPER AIRWAY PASSAGE DISEASES,” to Joel A. Sequeira, Francis M. Cuss, Keith B. Nolop, Imtiaz A. Chaudry, Nagamani Nagabhushan, James E. Patrick, and Mitchell Cayen.

**REPLY:** Admitted.

9. On or about October 3, 2000, the PTO issued U.S. Patent No. 6,127,353 (“the ‘353 patent”), entitled “MOMETASONE FUROATE MONOHYDRATE, PROCESS FOR MAKING SAME AND PHARMACEUTICAL COMPOSITIONS,” to Pui-Ho Yuen, Charles Eckhart, Teresa Etlinger, and Nancy Levine.

**REPLY:** Admitted.

10. On or about April 20, 2004, the PTO issued U.S. Patent No. 6,723,713 (“the ‘713 patent”), entitled “USE OF MOMETASONE FUROATE FOR TREATING UPPER AIRWAY PASSAGE DISEASES,” to Joel A. Sequeira, Francis M. Cuss, Keith B. Nolop, Imtiaz A. Chaudry, Nagamani Nagabhushan, James E. Patrick, and Mitchell Cayen.

**REPLY:** Admitted.

11. Schering purports and claims to own the ‘699, ‘353, and ‘713 patents.

**REPLY:** Schering admits that it is the owner of the ‘699, ‘353, and ‘713 patents.

12. On or about December 18, 2009, Schering sued Apotex in this District alleging infringement of the ‘699, ‘353, and ‘713 patents.

**REPLY:** Admitted.

**ALLEGED COUNT I**

**(Declaratory Judgment of Non-Infringement of the '699 Patent)**

13. Apotex re-asserts and re-alleges each of the foregoing paragraphs as if fully set forth herein.

**REPLY:** Schering repeats and realleges its responses to the allegations of the foregoing paragraphs as if fully set forth herein.

14. The manufacture, use, sale, offer for sale, or importation of the Mometasone Furoate Nasal Spray, 50 mcg, product that is the subject of Apotex Inc.'s ANDA has not infringed, does not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '699 patent, either directly or indirectly.

**REPLY:** Denied.

15. Schering maintains – and Apotex denies – that the manufacture, use, sale, offer for sale, or importation of the Mometasone Furoate Nasal Spray, 50 mcg, product that is the subject of Apotex Inc.'s ANDA stent has infringed, does infringe, or would infringe the '699 patent.

**REPLY:** The filing of ANDA No. 91-161 constituted an act of infringement of the '699 patent. Apotex filed ANDA No. 91-161 to obtain approval to engage in the commercial manufacture, use, or sale of a drug product which is claimed by the '699 patent before the expiration of the '699 patent. Schering lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 15 (including the reference to "Apotex Inc.'s ANDA stent"), and Schering therefore denies these allegations.

16. There is an actual, substantial, and continuing justiciable case or controversy between Apotex and Schering having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaratory judgment regarding Apotex's non-infringement of the '699 patent.

**REPLY:** Schering admits that a controversy exists between the parties but denies the remaining allegations of Paragraph 16.

17. Apotex is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, or importation of the Mometasone Furoate Nasal Spray, 50 mcg, product that is the subject

of Apotex Inc.'s ANDA has not infringed, does not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '699 patent, either directly or indirectly.

**REPLY:** Denied.

**ALLEGED COUNT II**

**(Declaratory Judgment of Invalidity of the '699 Patent)**

18. Apotex re-asserts and re-alleges each of the foregoing paragraphs as if fully set forth herein.

**REPLY:** Schering repeats and realleges its responses to the allegations of the foregoing paragraphs as if fully set forth herein.

19. The claims of the '699 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Code.

**REPLY:** Denied.

20. Schering maintains – and Apotex denies – that the claims of the '699 patent are valid.

**REPLY:** Schering admits that the claims of the '699 patent are valid. Schering lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 20, and Schering therefore denies these allegations.

21. There is an actual, substantial, and continuing justiciable case or controversy between Apotex and Schering having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaratory judgment regarding the invalidity of the '699 patent.

**REPLY:** Schering admits that a controversy exists between the parties but denies the remaining allegations of Paragraph 21.

22. Apotex is entitled to a judicial declaration that the claims of the '699 patent are invalid.

**REPLY:** Denied.

**ALLEGED COUNT III**

**(Declaratory Judgment of Non-Infringement of the '353 Patent)**

23. Apotex re-asserts and re-alleges each of the foregoing paragraphs as if fully set forth herein.

**REPLY:** Schering repeats and realleges its responses to the allegations of the foregoing paragraphs as if fully set forth herein.

24. The manufacture, use, sale, offer for sale, or importation of the Mometasone Furoate Nasal Spray, 50 mcg, product that is the subject of Apotex Inc.'s ANDA has not infringed, does not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '353 patent, either directly or indirectly.

**REPLY:** Denied.

25. Schering maintains – and Apotex denies – that the manufacture, use, sale, offer for sale, or importation of the Mometasone Furoate Nasal Spray, 50 mcg, product that is the subject of Apotex Inc.'s ANDA stent has infringed, does infringe, or would infringe the '353 patent.

**REPLY:** The filing of ANDA No. 91-161 constituted an act of infringement of the '353 patent. Apotex filed ANDA No. 91-161 to obtain approval to engage in the commercial manufacture, use, or sale of a drug product which is claimed by the '353 patent before the expiration of the '353 patent. Schering lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 25 (including the reference to "Apotex Inc.'s ANDA stent"), and Schering therefore denies these allegations.

26. There is an actual, substantial, and continuing justiciable case or controversy between Apotex and Schering having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaratory judgment regarding Apotex's non-infringement of the '353 patent.

**REPLY:** Schering admits that a controversy exists between the parties but denies the remaining allegations of Paragraph 26.

27. Apotex is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, or importation of the Mometasone Furoate Nasal Spray, 50 mcg, product that is the subject of Apotex Inc.'s ANDA has not infringed, does not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '353 patent, either directly or indirectly.

**REPLY:** Denied.

**ALLEGED COUNT IV**

**(Declaratory Judgment of Invalidity of the '353 Patent)**

28. Apotex re-asserts and re-alleges each of the foregoing paragraphs as if fully set forth herein.

**REPLY:** Schering repeats and realleges its responses to the allegations of the foregoing paragraphs as if fully set forth herein.

29. The claims of the '353 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Code.

**REPLY:** Denied.

30. Schering maintains – and Apotex denies – that the claims of the '353 patent are valid.

**REPLY:** Schering admits that the claims of the '699 patent are valid. Schering lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 30, and Schering therefore denies these allegations.

31. There is an actual, substantial, and continuing justiciable case or controversy between Apotex and Schering having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaratory judgment regarding the invalidity of the '353 patent.

**REPLY:** Schering admits that a controversy exists between the parties but denies the remaining allegations of Paragraph 31.

32. Apotex is entitled to a judicial declaration that the claims of the '353 patent are invalid.

**REPLY:** Denied.

**ALLEGED COUNT V**

**(Declaratory Judgment of Non-Infringement of the '713 Patent)**

33. Apotex re-asserts and re-alleges each of the foregoing paragraphs as if fully set forth herein.



**REPLY:** Schering repeats and realleges its responses to the allegations of the foregoing paragraphs as if fully set forth herein.

34. The manufacture, use, sale, offer for sale, or importation of the Mometasone Furoate Nasal Spray, 50 mcg, product that is the subject of Apotex Inc.'s ANDA has not infringed, does not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '713 patent, either directly or indirectly.

**REPLY:** Denied.

35. Schering maintains – and Apotex denies – that the manufacture, use, sale, offer for sale, or importation of the Mometasone Furoate Nasal Spray, 50 mcg, product that is the subject of Apotex Inc.'s ANDA stent has infringed, does infringe, or would infringe the '713 patent.

**REPLY:** The filing of ANDA No. 91-161 constituted an act of infringement of the '713 patent. Apotex filed ANDA No. 91-161 to obtain approval to engage in the commercial manufacture, use, or sale of a drug product which is claimed by the '713 patent before the expiration of the '713 patent. Schering lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 35 (including the reference to "Apotex Inc.'s ANDA stent"), and Schering therefore denies these allegations.

36. There is an actual, substantial, and continuing justiciable case or controversy between Apotex and Schering having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaratory judgment regarding Apotex's non-infringement of the '713 patent.

**REPLY:** Schering admits that a controversy exists between the parties but denies the remaining allegations of Paragraph 36.

37. Apotex is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, or importation of the Mometasone Furoate Nasal Spray, 50 mcg, product that is the subject of Apotex Inc.'s ANDA has not infringed, does not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '713 patent, either directly or indirectly.

**REPLY:** Denied.

#### **ALLEGED COUNT VI**



**(Declaratory Judgment of Invalidity of the '713 Patent)**

38. Apotex re-asserts and re-alleges each of the foregoing paragraphs as if fully set forth herein.

**REPLY:** Schering repeats and realleges its responses to the allegations of the foregoing paragraphs as if fully set forth herein.

39. The claims of the '713 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Code, and/or for obviousness-type double patenting.

**REPLY:** Denied.

40. Schering maintains – and Apotex denies – that the claims of the '713 patent are valid.

**REPLY:** Schering admits that the claims of the '699 patent are valid. Schering lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 40, and Schering therefore denies these allegations.

41. There is an actual, substantial, and continuing justiciable case or controversy between Apotex and Schering having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaratory judgment regarding the invalidity of the '713 patent.

**REPLY:** Schering admits that a controversy exists between the parties but denies the remaining allegations of Paragraph 41.

42. Apotex is entitled to a judicial declaration that the claims of the '713 patent are invalid.

**REPLY:** Denied.

Schering denies all allegations and statements not expressly admitted or responded to herein and further denies that Apotex is entitled to any of the relief requested, or to any relief at all.

**DEMAND FOR JURY TRIAL**

In their Counterclaims, Defendants “demand[ed] a trial by jury on all issues so triable.”

Schering denies that Defendants have any right to a trial by jury.

Dated: March 4, 2010

Respectfully submitted,

**GIBBONS P.C.**

One Gateway Center

Newark, New Jersey 07102-5310

Phone: (973) 596-4500

Facsimile: (973) 639-6235

By: s/ Sheila F. McShane

Sheila F. McShane

smcshane@gibbonslaw.com

OF COUNSEL:

Matthew D. Powers

**WEIL, GOTSHAL & MANGES, LLP**

201 Redwood Shores Parkway

Redwood Shores, California 94065

(650) 802-3000

Nicolas G. Barzoukas

Jason C. Abair

Joshua P. Davis

Audrey L. Maness

**WEIL, GOTSHAL & MANGES, LLP**

700 Louisiana, Suite 1600

Houston, Texas 77002

(713) 546-5000